Citation:

Lorenzen JK, Mølgaard C, Michaelsen KF, Astrup A. Calcium supplementation for 1 y does not reduce body weight or fat mass in young girls. Am J Clin Nutr. 2006 Jan;83(1):18-23.

PubMed ID: 16400044

Study Design:

Randomized double-blind placebo controlled trial

Class:

A - Click here for explanation of classification scheme.

Research Design and Implementation Rating:

NEUTRAL: See Research Design and Implementation Criteria Checklist below.

Research Purpose:

To examine whether calcium supplementation affects body weight and body fat during a period of one year in young girls and whether a relation exists between habitual calcium intake and body weight and body fat

Inclusion Criteria:

- Girls aged 12y±6 months from the Frederiksberg and Copenhagen municipalities with Danish names
- Calcium intake between 40th and 60th percentiles (1000-1304 mg/day) and calcium intake of less than 20th percentile (less than 713 mg/day)

Exclusion Criteria:

- Excluded if not included above

Description of Study Protocol:

Recruitment:

- The girls were recruited through the National Central Person Register. They received a food frequency questionnaire (FFQ) and were asked about their height, weight, and health.
- Two groups were selected according to their intake of dietary calcium:
  - the median-calcium (MC) group with calcium intake between 1000-1303 mg/day and
  - the low-calcium (LC) group with intake less than 713 mg/day.

Design: Randomized, double-blind, placebo controlled trial

Blinding used (if applicable); Double-blind

Intervention (if applicable): Calcium carbonate (500mg/day) vs placebo

Statistical Analysis:

- Independent-samples T-test : comparisons betwee 2 groups
- ANCOVA was used to examine the effect of calcium supplementation. The two intervention groups (calcium tablet or placebo) and the two dietary groups (median-calcium and low-calcium) were independent variables and either baseline values alone, or baseline values and protein intake at one year were included as covariates
- Pearson correlation coeficient and linear regression.
- Adjusted R^2 was used to assess how well the linear regression model predicted the dependent variable
- A P value <0.05 was considered significant

Data Collection Summary:

Timing of Measurements: The food frequency questionnaire (FFQ) for dietary intake of calcium and protein was assessed at recruitment, at baseline, and after one year. Anthropometric and biochemical measures, body composition and pubertal development were measured at baseline and at one year.

Dependent Variables

- Weight (kg)
- Body fat (%) -Dual X-ray Absorptiometry (Hologic QDR-1000/W whole-body version 5.61)
- Lean body mass (%) DXA

Independent Variables

- Calcium supplementation- Girls from each of the two groups (MC and LC) were randomly assigned to receive either a daily calcium carbonate supplement of 500mg (calcium group) or a placebo tablet (placebo group)for one year.The girls were instructed to consume the supplement together with the evening meal. The tablets were delivered to the subjects's private address every third month, and surplus tablets from the previous period were collected. Compliance was evaluated by tablet counting
- Dietary calcium intake - It was estimated by using a FFQ. Calcium intake was expressed as intake of total dietary calcium and intake of dairy calcium. In addition, calcium was expressed as calcium:protein. Protein intake was used as an indicator for energy intake and adjustment for protein intake as an appoximate adjustment for energy intake.

Control Variables

- 25-Hydroxyvitamin D (mmol/L)
- Protein intake
- Menarche

Description of Actual Data Sample:

Initial N: 113

Attrition (final N):110 (60MC group; 50LC group)

Age: mean age 13 years old

Ethnicity: not reported

Other relevant demographics:

Anthropometrics: Groups were well matched for height, wieght, body fat and lean body mass. The girls had normal weights.

- Weight (kg):
  - Calcium group:
    - MC: 51.8±1.7
    - LC: 52.2±1.7
  - Placebo group:
    - MC: 50.7±1.6
    - LC: 49.5±1.7
- % body fat:
  - Calcium group:
    - MC: 22.6±0.9
    - LC: 24.6±1.0
  - Placebo group:
    - MC: 21.7±0.7
    - LC: 24.5±1.1

Location: Copenhagem, Denmark

Summary of Results:

Key Findings

- Calcium supplementation had no effect on height (P=0.868), body weight (P=0.249), body fat (P=0.384), or lean body mass (P=0.358). The results were not affected by inclusion of protein intake as a covariate as well
- At baseline a negative correlation was observed between intake of dietary calcium and percentage of body fat (r=-0.242, P=0.011)
- A similar negative correlation was also observed between percentage of body fat and intake of dairy calcium (r=-0.218,P=0.022) and calcium:protein (r=-0.274,P=0.004)
- Intake of dietary calcium could explain 5% of the variation in percentage of body fat (constant=25.585±1.016, P<0.001; calcium intake =-0.002±0.001. P<0.001; R2 adjusted =0.05)
- No signficant correlation was observed between body weight and intake of dietary calcium (r=0.072,P=0.453), intake of dairy calcium (r=0.077,P=0.424), or dietary calcium:proteion (r=0.041,P=0.674) at baseline

Other Findings

- Calcium supplementation had a positive effect on total calcium intake (dietary plus supplement) at one year (P<0.001) but not on intake of dietary calcium, intake of dairy

calcium, dietary protein, or intake of dietary calcium and protein
- The MC group had a sginificantly higher dietary calcium and protein intake than the LC group; P<0.0001
- No significant correlation was observed between change in calcium intake from baseline to one year and change in percentage of body fat.

Author Conclusion:

Habitual intake of dietary calcium was inversely associated with body fat, but a low-dose calcium suppementation had no effect on body weight, height, or body fat during a period of one year in young girls. It is possible that the effect of calcium on body weight is only exerted if it is ingested as part of a meal. Alternatively, the effect may be due to other ingredients in dairy products, and calcium may simply be a marker for a high dairy intake.

Reviewer Comments:

Self-reported questionnaire. Recognized limitations by the authors:

- *The study was not originally designed to evaluate the effect of calcium on body weight and body composition and had therefore some limitations that should be underscored*
- *Statistical power was limited due to the relatively few subjects participating in the study. It was calculated that the sample size was sufficient to detect a difference in percentage of body fat of 3% or higher. To detect a smaller difference, a larger sample size should be included*
- *Data on energy intake was not collected in this study, therefore, its was not possible to adjust for energy intake*
- *The subjects were all normal weight. It is possible that an effect of the intervention would be seen if the subjects were overweight or obese*

Research Design and Implementation Criteria Checklist: Primary Research

Relevance Questions

1.	Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patients/clients/population group? (Not Applicable for some epidemiological studies)	N/A
2.	Did the authors study an outcome (dependent variable) or topic that the patients/clients/population group would care about?	Yes
3.	Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to nutrition or dietetics practice?	Yes
4.	Is the intervention or procedure feasible? (NA for some epidemiological studies)	Yes

Validity Questions

1.	**Was the research question clearly stated?**	Yes
1.1.	Was (were) the specific intervention(s) or procedure(s) [independent variable(s)] identified?	Yes
1.2.	Was (were) the outcome(s) [dependent variable(s)] clearly indicated?	Yes
1.3.	Were the target population and setting specified?	Yes
2.	**Was the selection of study subjects/patients free from bias?**	No
2.1.	Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study?	No
2.2.	Were criteria applied equally to all study groups?	???
2.3.	Were health, demographics, and other characteristics of subjects described?	Yes
2.4.	Were the subjects/patients a representative sample of the relevant population?	No
3.	**Were study groups comparable?**	Yes
3.1.	Was the method of assigning subjects/patients to groups described and unbiased? (Method of randomization identified if RCT)	Yes
3.2.	Were distribution of disease status, prognostic factors, and other factors (e.g., demographics) similar across study groups at baseline?	Yes
3.3.	Were concurrent controls used? (Concurrent preferred over historical controls.)	N/A
3.4.	If cohort study or cross-sectional study, were groups comparable on important confounding factors and/or were preexisting differences accounted for by using appropriate adjustments in statistical analysis?	N/A
3.5.	If case control or cross-sectional study, were potential confounding factors comparable for cases and controls? (If case series or trial with subjects serving as own control, this criterion is not applicable. Criterion may not be applicable in some cross-sectional studies.)	N/A
3.6.	If diagnostic test, was there an independent blind comparison with an appropriate reference standard (e.g., "gold standard")?	N/A
4.	**Was method of handling withdrawals described?**	No
4.1.	Were follow-up methods described and the same for all groups?	Yes
4.2.	Was the number, characteristics of withdrawals (i.e., dropouts, lost to follow up, attrition rate) and/or response rate (cross-sectional studies) described for each group? (Follow up goal for a strong study is 80%.)	No

4.3.	Were all enrolled subjects/patients (in the original sample) accounted for?	No
4.4.	Were reasons for withdrawals similar across groups?	???
4.5.	If diagnostic test, was decision to perform reference test not dependent on results of test under study?	N/A
5.	**Was blinding used to prevent introduction of bias?**	Yes
5.1.	In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate?	Yes
5.2.	Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.)	Yes
5.3.	In cohort study or cross-sectional study, were measurements of outcomes and risk factors blinded?	N/A
5.4.	In case control study, was case definition explicit and case ascertainment not influenced by exposure status?	N/A
5.5.	In diagnostic study, were test results blinded to patient history and other test results?	N/A
6.	**Were intervention/therapeutic regimens/exposure factor or procedure and any comparison(s) described in detail? Were interveningfactors described?**	Yes
6.1.	In RCT or other intervention trial, were protocols described for all regimens studied?	Yes
6.2.	In observational study, were interventions, study settings, and clinicians/provider described?	N/A
6.3.	Was the intensity and duration of the intervention or exposure factor sufficient to produce a meaningful effect?	Yes
6.4.	Was the amount of exposure and, if relevant, subject/patient compliance measured?	Yes
6.5.	Were co-interventions (e.g., ancillary treatments, other therapies) described?	N/A
6.6.	Were extra or unplanned treatments described?	N/A
6.7.	Was the information for 6.4, 6.5, and 6.6 assessed the same way for all groups?	N/A
6.8.	In diagnostic study, were details of test administration and replication sufficient?	N/A
7.	**Were outcomes clearly defined and the measurements valid and reliable?**	Yes
7.1.	Were primary and secondary endpoints described and relevant to the question?	Yes
7.2.	Were nutrition measures appropriate to question and outcomes of concern?	No

	7.3.	Was the period of follow-up long enough for important outcome(s) to occur?	Yes
	7.4.	Were the observations and measurements based on standard, valid, and reliable data collection instruments/tests/procedures?	Yes
	7.5.	Was the measurement of effect at an appropriate level of precision?	Yes
	7.6.	Were other factors accounted for (measured) that could affect outcomes?	No
	7.7.	Were the measurements conducted consistently across groups?	Yes
8.	**Was the statistical analysis appropriate for the study design and type of outcome indicators?**		Yes
	8.1.	Were statistical analyses adequately described and the results reported appropriately?	Yes
	8.2.	Were correct statistical tests used and assumptions of test not violated?	No
	8.3.	Were statistics reported with levels of significance and/or confidence intervals?	Yes
	8.4.	Was "intent to treat" analysis of outcomes done (and as appropriate, was there an analysis of outcomes for those maximally exposed or a dose-response analysis)?	No
	8.5.	Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g., multivariate analyses)?	Yes
	8.6.	Was clinical significance as well as statistical significance reported?	Yes
	8.7.	If negative findings, was a power calculation reported to address type 2 error?	N/A
9.	**Are conclusions supported by results with biases and limitations taken into consideration?**		Yes
	9.1.	Is there a discussion of findings?	Yes
	9.2.	Are biases and study limitations identified and discussed?	Yes
10.	**Is bias due to study's funding or sponsorship unlikely?**		???
	10.1.	Were sources of funding and investigators' affiliations described?	Yes
	10.2.	Was the study free from apparent conflict of interest?	???